

JUN 28 2012

510(k) Premarket Notification
CoRoent Titanium System**510(k) Summary**

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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Date Prepared: March 23, 2012

B. Device Name

| | |
|----------------------------|--|
| Trade or Proprietary Name: | <i>NuVasive CoRoent® Titanium System</i> |
| Common or Usual Name: | Intervertebral Body Fusion Device, Spinal Vertebral Body Replacement Device |
| Classification Name: | Intervertebral Body Fusion Device, Spinal Vertebral Body Replacement Device |

| | |
|-----------------|-------------------------------|
| Device Class: | Class II |
| Classification: | 21 CFR § 888.3060, § 888.3080 |
| Product Code: | MAX, MQP |

C. Predicate Devices

The subject *NuVasive CoRoent Titanium System* is substantially equivalent to the following predicate device: NuVasive CoRoent System (K071795)

D. Device Description

The *NuVasive CoRoent Titanium System* is a lumbar interbody system manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3. The implants are available in a variety of sizes to suite the individual pathology and anatomical conditions of the patient. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

**E. Intended Use*****Intervertebral Body Fusion***

The NuVasive CoRoent Titanium System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion. The CoRoent Titanium System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

Partial Vertebral Body Replacement

The NuVasive CoRoent Titanium System may also be used as a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent Titanium System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function.

G. Performance Data

Finite Element Analysis (FEA) was performed to demonstrate that the subject *CoRoent Titanium System* is substantially equivalent to other predicate devices for the following:

- Axial Compression
- Compression Shear
- Torsion
- Subsidence

The results demonstrate that the subject *CoRoent Titanium System* presents no new worst-case for performance testing, and the subject device was therefore found to be substantially equivalent to the predicate.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *CoRoent Titanium System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 28 2012

NuVasive, Inc.
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K120918
Trade/Device Name: NuVasive CoRoent® Titanium System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: June 6, 2012
Received: June 7, 2012

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

for [Signature]
Mark N. Melkerson *Asst Com Dir*
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: NuVasive® CoRoent® Titanium System

Indications For Use:

Intervertebral Body Fusion

The NuVasive CoRoent Titanium System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion. The CoRoent Titanium System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

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Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120918